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Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade

Chemical Review Committee
Fourteenth meeting
Rome, 11–14 September 2018
Item 4 (a) (i) of the provisional agenda**

Technical work: consideration of draft decision guidance documents: acetochlor

Draft decision guidance document for acetochlor

Note by the Secretariat

I. Introduction

1. At its thirteenth meeting, the Chemical Review Committee reviewed notifications of final regulatory action for acetochlor submitted by the European Union and 10 African parties – Burkina Faso, Cabo Verde, Chad, the Gambia, Guinea-Bissau, Mali, Mauritania, the Niger, Senegal and Togo – together with the supporting documentation referenced therein, and concluded that the notifications met all the criteria of Annex II to the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade.

2. In its decision CRC-13/1, the Committee recommended that the Conference of the Parties list acetochlor in Annex III to the Convention as a pesticide. In the same decision, the Committee adopted a rationale for its conclusions, decided to prepare a draft decision guidance document for acetochlor and also decided on the composition of the intersessional drafting group to prepare the document. A detailed workplan for the development of the decision guidance document was prepared by the Committee, in line with the process adopted by the Conference of the Parties by decision RC-2/2 and amended by decisions RC-6/3 and RC-7/3. The recommendation, rationale and workplan were annexed to the report of the Committee on the work of its thirteenth meeting (UNEP/FAO/RC/CRC.13/19, annexes I and III).

3. The material available to the intersessional drafting group included a summary of the outcome of the thirteenth meeting of the Committee, a copy of the working paper on the preparation of internal proposals and decision guidance documents for banned and severely restricted chemicals and the notifications of final regulatory action and associated supporting documentation available to the Committee at its thirteenth meeting.

4. In accordance with the agreed workplan, Ms. Parvoleta Angelova Luleva (Germany), the chair of the intersessional drafting group, and Ms. Leonarda Christina van Leeuwen (Netherlands), the vice-chair, prepared an internal proposal based on the notifications and the supporting documentation. That internal proposal was circulated to the members of the drafting group for comment on 14 December 2017. It was amended in the light of the comments received and was circulated on 16 February 2018 to all Committee members and to the observers who had attended the thirteenth meeting. Responses were received from Committee members and observers and taken into consideration in the preparation of the draft decision guidance document.

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* Reissued for technical reasons on 06 August 2018.

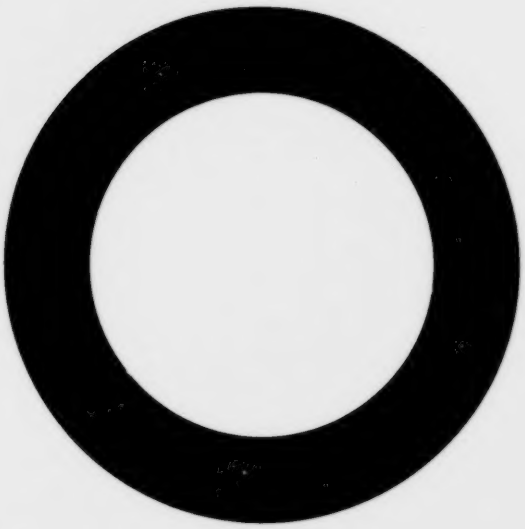
** UNEP/FAO/RC/CRC.14/1.

5. The draft decision guidance document and a compilation of the comments received were circulated to the members of the drafting group on 27 April 2018.

6. The text of the draft decision guidance document, as submitted by the drafting group, is set out in the annex to the present note. It has not been formally edited. A tabular summary of the comments received, including information on how they were addressed, is set out in the annex to the note by the Secretariat on the matter (UNEP/FAO/RC/CRC.14/INF/6).

II. Proposed action

7. The Committee may wish to finalize the draft decision guidance document and to forward it, together with its recommendation to list acetochlor in Annex III to the Convention as a pesticide, for consideration by the Conference of the Parties at its ninth meeting.



Annex

Rotterdam Convention

Operation of the prior informed consent procedure for banned or severely restricted chemicals

Draft Decision Guidance Document

Acetochlor

Secretariat of the Rotterdam Convention
on the Prior Informed Consent Procedure
for Certain Hazardous Chemicals and Pesticides
in International Trade

Food and Agriculture
Organization of the
United Nations

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Disclaimer

The use of trade names in the present document is primarily intended to facilitate the correct identification of the chemical. It is not intended to imply any approval or disapproval of any particular company. As it is not possible to include all trade names presently in use, only a number of commonly used and published trade names have been included in the document.

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Standard core set of abbreviations[3]

STANDARD CORE SET OF ABBREVIATIONS	
<	less than
≤	less than or equal to
>	greater than
≥	greater than or equal to
µg	microgram
µm	micrometre
ARfD	acute reference dose
a.i.	active ingredient
ADI	acceptable daily intake
AOEL	acceptable operator exposure level
b.p.	boiling point
bw	body weight
°C	degree Celsius (centigrade)
CAS	Chemical Abstracts Service
cc	cubic centimetre
cm	centimetre
DNA	deoxyribose nucleic acid
DT_{50}	dissipation time 50%
EC	European Community
EC_{50}	median effective concentration
ED_{50}	median effective dose
EEC	European Economic Community
EHC	Environmental Health Criteria
EU	European Union
EFSA	European Food Safety Authority
FAO	Food and Agriculture Organization of the United Nations
g	gram
h	hour
ha	hectare
i.m.	intramuscular
i.p.	intraperitoneal
IARC	International Agency for Research on Cancer
IC_{50}	median inhibitory concentration
ILO	International Labour Organization
IPCS	International Programme on Chemical Safety
IPM	Integrated Pest Management
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint FAO/WHO Meeting on Pesticide Residues (Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and a WHO Expert Group on Pesticide Residues)

[3] *This core list should serve as the basis for DGDs for industrial chemicals, pesticides and severely hazardous pesticide formulations. It should be augmented by abbreviations used in the individual DGDs relevant to the chemical(s) in question.*

Definitions and spelling should, as far as practicable, follow the IUPAC glossary of terms in toxicology and the IUPAC glossary of terms relating to pesticides in their current editions.

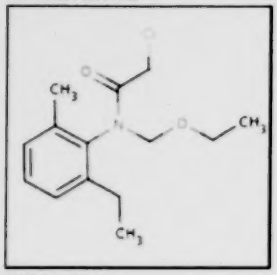
As a general rule it is preferable that acronyms used only once in the text be spelled out rather than included in the list of abbreviations.

STANDARD CORE SET OF ABBREVIATIONS	
k	kilo- (x 1000)
kg	kilogram
Koc	soil organic partition coefficient.
Kow	octanol–water partition coefficient
kPa	kilopascal
L	litre
LC_{50}	median lethal concentration
LD_{50}	median lethal dose
LOAEL	lowest-observed-adverse-effect level
LOEL	Lowest-observed-effect level
m	metre
m.p.	melting point
mg	milligram
ml	millilitre
mPa	millipascal
MRL	maximum residue limit
MTD	Maximum Tolerated Dose
ng	nanogram
NOAEC	no-observed-adverse-effect concentration
NOAEL	no-observed-adverse-effect level
NOEC	no-observed-effect concentration
NOEL	no-observed-effect level
OECD	Organisation for Economic Co-operation and Development
PEC	predicted environmental concentration
Pow	octanol-water partition coefficient, also referred to as Kow
PPE	personal protective equipment
ppm	parts per million (used only with reference to the concentration of a pesticide in an experimental diet. In all other contexts the terms mg/kg or mg/L are used).
RAC	Risk Assessment Committee of the European Chemicals Agency
RMS	Rapporteur Member State
RfD	reference dose (for chronic oral exposure; comparable to ADI)
SMR	standard(ized) mortality ratio
STEL	short-term exposure limit
TER	toxicity exposure ratio
TLV	threshold limit value
TWA	time-weighted average
UNEP	United Nations Environment Programme
USEPA	United States Environmental Protection Agency
UV	ultraviolet
VOC	volatile organic compound
w/w	weight for weight
WHO	World Health Organization
wt	weight

Decision guidance document for a banned or severely restricted chemical

Acetochlor **Published:**

1. Identification and uses (see Annex 1 for further details)

Common name	acetochlor
Chemical name and other names or synonyms	**IUPAC:** 2-chloro-N-ethoxymethyl-6'-ehtylacet-*o*-toluidide **CA:** 2-chloro-N-(ethoxymethyl)-N-(2-ethyl-6-methylphenyl)acetamide
Molecular formula	C14H20ClN02
Chemical structure	
CAS-No.(s)	34256-82-1
Harmonized System Customs Code	2924.29
Other numbers	**EINECS:** 251-899-3
Category	Pesticide
Regulated category	Pesticide
Use(s) in regulated category	Acetochlor has been used in the European Union as a herbicide on maize to control weeds through broadcast spraying. Acetochlor has been used as a selective herbicide on maize in the CILSS countries.
Trade names	Trade names listed by the EU: Acenit, Guardian, Harness, Relay, Sacemid, Surpass, Top-Hand, Trophy and Winner Trade names listed by the Burkina Faso, Cabo Verde, Chad, the Gambia, Guinea-Bissau, Mali, Mauritania, the Niger, Senegal and Togo: ACEDAF 400 EC, ACEPROMAÏS 400 SC, ACEPRONET 400 EC, ACETO 900 EC, ACETOCAL 900 EC, HERBISUPER KEYTOCHLORE 900 EC *This is an indicative list. It is not intended to be exhaustive.*
Formulation types	Capsule suspension (CS), Emulsifiable concentrate (EC) *This is an indicative list. It is not intended to be exhaustive.*
Uses in other categories	None
Basic manufacturers	Dow AgroSciences, Monsanto Service International S.A *This is an indicative list of current and former manufacturers. It is not intended to be exhaustive.*

2. Reasons for inclusion in the PIC procedure

Acetochlor is included in the PIC procedure as a pesticide. It is listed on the basis of the final regulatory actions taken by Burkina Faso, Cabo Verde, Chad, the Gambia, Guinea-Bissau, Mali, Mauritania, the Niger, Senegal, Togo (hereafter referred to as the CILSS countries) and the European Union to ban the use of acetochlor as a pesticide.

No final regulatory actions relating to uses as industrial chemical have been notified.

2.1 Final regulatory action (see Annex 2 for further details)

CILSS countries

The ten Parties from the African region are members of the Sahelian Pesticides Committee. As the members of the Committee work together to take decisions on the registration of pesticides on a regional basis, the notifications submitted by these Parties refer to the same final regulatory action.

Decision N°002/MC/2017 bans all products containing acetochlor and entered into force on 20 March 2017. The import, manufacture for domestic use, distribution and sale have also been banned.

Reason: Human health and the environment

European Union

It is prohibited to place on the market or use plant protection products containing acetochlor in the European Union (Commission Implementing Regulation (EU) No 1372/2011 of 21 December 2011 concerning the non-approval of the active substance acetochlor, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending Commission Decision 2008/934/EC (Official Journal of the European Union L 341, 22.12.2011, p. 45-46)). Acetochlor is not approved for placing on the market pursuant to Regulation (EC) No. 1107/2009 concerning the placing of plant protection products on the market (which replaces Directive 91/414/EEC). All authorisations for plant protection products containing acetochlor had to be withdrawn by the Member States by 23 June 2012 and all uses of plant protection products containing acetochlor are prohibited as of 23 June 2013 at the latest.

Reason: Human health and the environment

2.2 Risk evaluation (see Annex 1 for further details)

CILSS countries

The final regulatory action (Decision N 002/MC/2017) to ban all products containing acetochlor in the Sahel countries was based on a risk evaluation and took into account scientific information from a variety of sources.

The CILSS countries found that acetochlor caused great difficulties for users in the CILSS countries to use acetochlor without unacceptable risk to human health and the environment. The risks to human health (by contamination of groundwater and surface water which are both used as drinking water), operators (due to the absence of sufficient personal protection measures) and to the environment (due to the intrinsic properties of the substance, the risk of water contamination and the specific conditions in the Sahel) make it difficult to use acetochlor safely.

The risk evaluation took into account the conditions within the notifying Parties, for example the conditions of application of the substance, the availability of personal protective equipment, and the regional environmental circumstances and identified the following concerns:

Human health

- Potential risk for human exposure through surface and ground water contamination by the metabolite t-norchloro acetochlor, which is genotoxic[4]: ground water is used as drinking water reservoir for humans and surface water is used as drinking water for humans and animals;
- Difficulties for the population in finding suitable personal protective equipment;
- Absence of an environmental management system respecting buffer strips between treated fields and streams. Since this precaution is not possible in the Sahel, the use of acetochlor entails an unacceptable risk to human health and the environment.

Environment

- High risk of surface and groundwater contamination by acetochlor and its metabolites;
- High risk to non-target terrestrial plants;
- Long term high risk to herbivorous birds;
- Surface water contamination and high risk to aquatic organisms;
- High short-term risk to birds drinking contaminated water following post emergence treatment;
- The fragile ecology of CILSS countries, sometimes characterised by torrential rainfall on soils which are very often poor in organic matter and therefore subject to erosion and leaching;

[4] Conclusion from CILSS countries based on EFSA (2011), which indicates that t-norchloro acetochlor (t-NCA) has genotoxic potential. In the EFSA review, 4 studies on the genotoxicity of t-NCA were cited, one showing doubtful, one showing positive and one showing negative results. Also see Annex 1 section 2.2.3

- Risk of soil impoverishment in the Sahel;
- Absence of an environmental management system respecting buffer strips between treated fields and streams. Since this precaution is not possible in the Sahel, the use of acetochlor entails an unacceptable risk to human health and the environment.

European Union

A risk assessment was carried out on the basis of Directive 91/414/EEC (replaced by Regulation (EC) No 1107/2009), which provides for the European Commission to issue a work programme for the examination of existing active substances used in plant protection products with a view to their possible inclusion in Annex I to the Directive, and in accordance with the provisions of Regulation (EC) No 1095/2007 and Regulation (EC) No 2229/2004. A Member State was designated to undertake the risk assessment based on the information submitted by the applicant and to establish a draft assessment report, which was subject to peer review during which the European Food Safety Authority (EFSA) undertook consultations with experts from Member States as well as with the applicant.

The EU risk assessment took into account the proposed conditions of use of acetochlor within the EU, including the intended uses, recommended application rates and good agricultural practices. The conclusion on the peer review was reached on the basis of the evaluation of the notified representative uses as an herbicide on maize in the EU.

For some criteria in the risk evaluation, it was not demonstrated that the risks were acceptable due to the lack of information; in particular the information available was not sufficient to conclude on the risk assessment for the groundwater contamination for metabolites t-norchloroacetochlor and t-hydroxyacetochlor.

However, evaluations made by the designated RMS and EFSA on the basis of the available information demonstrated that the following concerns for human health and the environment were identified under the proposed conditions of use in the EU:

Human health

- The potential human exposure is above 100% of the ADI when predicted concentrations of the ground water metabolites t-oxanilic acid, t-sulfinylacetic acid, t-sulfonic acid and s-sulfonic acid that have been concluded as relevant metabolites are taken into account.
- There is a potential human exposure to metabolite t-norchloro acetochlor when surface water is abstracted for drinking water, which has been concluded as relevant from a toxicological hazard assessment perspective. In addition, the toxicological data for t-norchloro acetochlor indicate that it is genotoxic.
- A high potential for groundwater contamination has been identified over significant areas of the EU by the metabolites t-oxanilic acid, t-sulfinylacetic acid, t-sulfonic acid and s-sulfonic acid, which have been concluded as relevant metabolites.
- No valid method has been available to quantify residues in food of plant origin.

Environment

- Acetochlor is very toxic to all groups of aquatic organisms and there is a high risk to aquatic organisms.
- A high acute risk to birds from uptake of contaminated drinking water was indicated for the post emergence applications.
- There is a high risk to non-target terrestrial plants. The risk assessment suggests that an in-field no spray buffer zone of 5m is required to protect non target plants in the off-field area.
- A high long term risk for herbivorous birds has been identified.

3. Protective measures that have been applied concerning the chemical

3.1 Regulatory measures to reduce exposure

CILSS countries	The final regulatory action of the Parties bans the use of acetochlor as an active ingredient in plant protection products. The final regulatory actions are expected to lead to a significant decrease in the quantity of the chemical used, resulting in significant reduction of the exposure of humans and the environment. The reduction in exposure to the chemical will lead to reduction of risk caused by acetochlor to human health and the environment.
European Union	The final regulatory action of the Parties bans the use of acetochlor as an active ingredient in plant protection products. The final regulatory actions are expected to lead to a significant decrease in the quantity of the chemical used, resulting in significant reduction of the exposure of humans and the environment. The reduction in exposure to the chemical will lead to reduction of risk caused by acetochlor to human health and the environment.

3.2 Other measures to reduce exposure

CILSS countries

Not reported

European Union

Not reported

3.3 Alternatives

There are a number of alternative methods involving chemical and non-chemical strategies, including alternative technologies available, depending on the individual crop-pest complex under consideration. Countries should consider promoting, as appropriate, integrated pest management (IPM) and organic strategies as a means of reducing or eliminating the use of hazardous pesticides.

CILSS countries

1. Chemical alternatives

Alternatives to the use of acetochlor based formulations exist. Formulations of selective pesticides are registered and authorised for sale in CILSS countries. Several selective pesticides formulations can be found in the global list of pesticides registered by CSP for maize and cotton. (CSP, 2016, website: www.insah.org). These formulations belong to the following chemical classes: sulfonylurea (nicosulfuron), substituted ureas (diuron), toluidin (pendimethalin), etc.

2. Integrated production and pest management (IPPM)

IPPM experience initiative launched by FAO in collaboration with the Ministers of Agriculture in several Sahel countries allowed obtaining important results in agricultural production and pest management. This initiative of development and implementation of good agricultural practices (GAPs) allows to enhance agricultural productivity and to train several farmers as potential facilitators.

European Union

Not reported

3.4 Socio-economic effects

CILSS countries

No assessment of socio-economic effects was reported.

European Union

No assessment of socio-economic effects was reported.

4. Hazards and Risks to human health and the environment

4.1 Hazard Classification	
WHO / IPCS	III (slightly hazardous)
IARC	Not available
European Union	**Classification of the EU according to Regulation (EC) No 1272/2008 of the European Parliament and of the Council, as adopted pursuant to Commission Regulation (EU) 2016/1179** Carc. 2 - H351 (Suspected of causing cancer) Repr. 2 - H361f (Suspected of damaging fertility) Acute Tox. 4 - H332 (Harmful if inhaled) STOT SE 3 - H335 (May cause respiratory irritation) STOT RE 2 - H373 (kidney) May cause damage to organs through prolonged or repeated exposure Skin Irrit. 2 - H315 (Causes skin irritation) Skin Sens. 1 - H317 (May cause an allergic skin reaction) Aquatic Acute 1 - H400 (Very toxic to aquatic life) Aquatic Chronic 1 H410 (Very toxic to aquatic life with long lasting effects) (EU notification) *Reference: https://echa.europa.eu/information-on-chemicals/cl-inventory-database/-/discl/details/104340, accessed 26 April 2018*
US EPA	oral, dermal and eye irritation – III inhalation – IV dermal irritation – II and found to be a dermal sensitizer
Japan	According to the GHS classification approved by Japan, this substance is Carcinogenic category 1B, Reprotoxic category 2, Specific target organ toxicity – Repeated exposure : Category 1 (kidney, testis), Category 2 (central nervous system), Hazardous to the aquatic environment (acute and long-term) category 1 *Reference: http://www.safe.nite.go.jp/english/ghs/11-mhlw-00096e.html, accessed 26 April 2018*

4.2 Exposure limits

No internationally recognised exposure limits are available for this chemical. National exposure limits from the notifying countries are presented in Annex II.

4.3 Packaging and labelling	
The United Nations Committee of Experts on the Transportation of Dangerous Goods classifies the chemical in:	
Hazard Class and Packing Group:	Based on UN number 3082; Hazard class 9, UN Packing group III
International Maritime Dangerous Goods (IMDG) Code	Based on UN number 3082; Hazard class 9, UN Packing group III
Transport Emergency Card	Not available
Further specific guidance on appropriate symbols and label statements for acetochlor products may be available in the FAO Guidelines on Good Labelling Practice for Pesticides.	

4.4 First aid

Not available

NOTE: The following advice is based on information available from the World Health Organisation and the notifying countries and was correct at the time of publication. This advice is provided for information only and is not intended to supersede any national first aid protocols.

4.5 Waste management

Not available

Annexes

Annex 1	**Further information on the chemical**
Annex 2	**Details on final regulatory actions reported**
Annex 3	**Addresses of designated national authorities**
Annex 4	**References**

Annex 1 Further information on the chemical

Introduction

The information presented in this Annex reflects the conclusions of the notifying parties: Burkina Faso, Cabo Verde, Chad, the Gambia, Guinea-Bissau, Mali, Mauritania, the Niger, Senegal, Togo and the European Union. These notifications were published in PIC Circular XLV of June 2017.

Relevant information from WHO and FAO (JMPR, 2015) is included in the section 2.2.3 on genotoxicity (including mutagenicity) and 2.2.4 on long-term toxicity and carcinogenicity of this Annex. The JMPR report is from a more recent date (2015) than the information from the notifying countries and provides a different view on the genotoxicity and carcinogenicity of acetochlor.

Where possible, information on hazards provided by the notifying parties has been presented together, while the evaluation of the risks, which are specific to the conditions prevailing in the notifying Parties are presented separately.

1. Identity and Physico-Chemical properties

1.1	**Identity**	ISO: Acetochlor IUPAC: 2-chloro-N-ethoxymethyl-6'-ethylacet-*o*-toluidide CA: 2-chloro-N-(ethoxymethyl)-N-(2-ethyl-6-methylphenyl)acetamide
1.2	**Formula**	C14H20ClNO2
1.3	**Colour and Texture**	Pure material: pale yellow, free-flowing liquid (99.9%) Technical material: pale yellow, free-flowing liquid (95.0%)
1.4	**Decomposition temperature**	237-239°C (at 98.78 KPa) (99.9 %)
1.6	**Density (g/cm³)**	1.136 g/mL at 20 deg C; 1.107 g/mL at 25 deg C; 1.1 g/mL at 30 deg C
1.7	**Resistance to acids**	No information available.
1.8	**Resistance to alkalis**	No information available.
1.9	**Tensile strength (10^3 kg/cm²)**	No information available.

2 Toxicological properties

2.1	**General**	
2.1.1	**Mode of Action**	**CILSS Countries** Elongase inhibition, and inhibition of geranylgeranyl pyrophosphate (GGPP) cyclization enzymes, part of the gibberellin pathway. (Footprint PPDB, 2015; INERIS, 2013; (CILSS notification) Produces tumors of the nasal olfactory epithelium in rats by way of a non-linear, non-genotoxic mode of action that includes cytotoxicity of the olfactory epithelium, followed by regenerative cell proliferation of the nasal epithelium that can then lead to neoplasia if cytotoxicity and proliferation are sustained. Produces tumors of the thyroid follicular cells in rats by way of a non-genotoxic mode of action that includes UDPGT induction, increased TSH, alterations in T3/T4 hormone production and thyroid hyperplasia. (The Grouping of a Series of Chloroacetanilide Pesticides Based on a Common Mechanism of Toxicity (USEPA 2006) (CILSS notification).
2.1.2	**Symptoms of poisoning**	**CILSS Countries** Minor effects to the eyes and skin; No recommendations are made based on the limited information available. (US EPA, 2009) (CILSS notification).

2.1.3 Absorption, distribution, excretion and metabolism in mammals

Oral absorption is rapid and almost complete, based on urine and bile excretion in rat being >80% following repeated dosing at 10 mg/kg bw/day. It is widely distributed in the body but the potential for accumulation is low, although there is some accumulation in nasal turbinates in rat (but not in mice). The rate of excretion is relatively rapid (~86% within 48 hours), mainly in urine (66-72%) and in faeces (12-21%, of which 80-85% comes via the bile). Acetochlor undergoes conjugation and mixed function oxygenation with the main metabolite in rat and monkey being *tert*-mercapturic acid with 25-27% of the radioactivity excreted in monkey urine. (EFSA, 2011) (EU notification).

2.2 Toxicology studies

2.2.1 Acute toxicity

European Union

The acute toxicity of acetochlor after oral or inhalative administration is moderate (LD_{50} rats, oral = 1929 mg/kg body weight, LC_{50} rats, inhalation = 3.99 mg/l/4 h (exposure nose-only, test material aerosol)). It is irritating for the respiratory system and for the skin, as well as a skin sensitiser (LD_{50} (rat, dermal): >2000 mg/kg bw) (EFSA, 2011).

Acetochlor based formulations registered by CSP belong to WHO class III (moderately harmful) (CSP, 2014).

2.2.2 Short term toxicity

European Union

Three dietary studies in rats, four oral studies (dietary and capsules) in dog and two dermal studies in rats and rabbits are described. The dog is the most sensitive species with a NOAEL (52 -week dog study) of 2 mg/kg bw/d based on decreased body weight gain and histopathological findings in kidneys and testes observed at 10 mg/kg bw/day (EFSA, 2011).

2.2.3 Genotoxicity (including mutagenicity)

European Union

Positive and negative results have been reported *in vivo* and *in vitro* with technical material of low and high purity (from 89.9 to 96.7 %). Many *in vitro* studies show positive results. The *in vivo* UDS test shows positive results at toxic dose levels and clear negative results are found in micronucleus and dominant lethal studies. Experts agreed that the substance induces DNA repair synthesis *in vivo*, which was not considered as a clear indication of mutagenicity *in vivo* and they concluded that this does not affect the risk assessment (EFSA, 2011).

Genotoxicity of the metabolite t-norchloro acetochlor

The following studies are summarized in EFSA (2011):

Assay	Species	Result
In vitro gene mutation	Bacterial cells	Doubtful results in first assay
In vitro gene mutation	Mouse lymphoma cells	Positive
In vitro chromosome aberrations	Human lymphocytes	Negative (+/- S9)
In vitro chromosome aberrations	Mouse (micronucleus test)	Negative

It was concluded that "the groundwater metabolite t-norchloro acetochlor (6) is also toxicologically relevant based on its genotoxic (see table above) and carcinogenic potential (from acetochlor), and no reference values were agreed" (EFSA 2011).

WHO and FAO

Results for gene mutation assays are conflicting and provide no clear evidence of a positive effect in either bacterial or mammalian cell test systems. Similarly, the evidence from in vitro and in vivo unscheduled DNA synthesis assays, in vitro sister chromatid exchange studies and an in vivo comet test provides no convincing pattern of genotoxic activity. By contrast, results from chromosomal aberration assays indicate that acetochlor is a confirmed clastogen in cultured human lymphocytes. There is also the possibility that the increased mutant colony counts observed in the positive mouse lymphoma assay resulted from a clastogenic rather than a mutagenic response, as this test system can detect chromosome breakage. Nevertheless, clastogenicity is confined to in vitro mammalian cell test systems, and the types of induced aberrations suggest cytotoxicity. Based on data from three bone marrow assays and three dominant

lethal mutation studies in mice or rats, acetochlor-induced clastogenicity is not expressed in either somatic or germinal cells of whole animals (JMPR, 2015).

Genotoxicity of the metabolite t-norchloro acetochlor

In the JMPR report from 2015, the following studies are summarized:

Study	Test system	Purity (%)	Results	Reference
Bacterial gene mutation (Ames)	S. typhimurium TA98, TA100, TA1535 and TA1537; E. coli WP2 and WP2P uvrA	99.5	Negative	Callander (2002)
Bacterial gene mutation (Ames)	S. typhimurium TA98, TA100, TA1535 and TA1537; E. coli WP2 and WP2P uvrA	99	Negative	Wagner (2013)
In vitro mammalian gene mutation	Mouse lymphoma	99.5	Weakly positive (up to 2.6 times control)	Clay (2002)
In vitro chromosomal aberration	Human lymphocytes	99.5	Negative	Fox (2002)
In vivo micronucleus	Mouse (bone marrow)	99.5	Negative	Fox (2002b)
In vivo transgenic gene mutation	Mouse	> 99	Negative	Beevers (2014)

It was concluded that "No evidence of genotoxicity was observed in various in vivo and in vitro assays, except for a mouse lymphoma assay, which gave a weak positive response for two metabolites; however, these two metabolites were negative in a mouse micronucleus assay.

The Meeting concluded that these plant metabolites, soil degradates and environmental metabolites of acetochlor appear to be less toxic than the parent compound." (JMPR, 2015).

2.2.4 Long term toxicity and carcinogenicity

European Union

Long-term toxicity

Target/Critical effects: anaemia, kidney and liver toxicity (mice and rats).
Rat (diet, 2 year): NOAEL = 9.4 mg/kg bw/day
Mouse (diet, 78 week): LOAEL = 1.1 mg/kg bw/day (EFSA, 2011).

Carcinogenicity

Rat: adenomas in nasal epithelium at 47.5 mg/kg bw/day. Gastric tumours.
Mouse: lung adenomas and carcinomas, uterine histocytic sarcomas.
In conclusion, taking into account the different tumours observed in both species, the meeting agreed to propose the classification Carc. cat.3, R40 Limited evidence of a carcinogenic effect. (EFSA, 2011).

WHO and FAO

Rat: Adenomas in nasal epithelium

Mouse: Marginal increase in histiocytic sarcomas

Conclusion: Unlikely to pose a carcinogenic risk to humans from the diet. (JMPR, 2015)

2.2.5	**Effects on reproduction**	**European Union** Reproductive target/critical effect: *Parental*: decreased body weight, increased liver weight, nasal hyperplasia. *Offspring*: reduced litter and pup weight, delayed vaginal opening, increased relative brain weight. *Reproduction*: decreased number of implantations, decreased number of live pups. Relevant parental and offspring NOAEL: 20 mg/kg bw/day Relevant reproductive NOAEL: 61 mg/kg bw/day Developmental target/critical effect: *Maternal*: decreased bodyweight gain, (rat, rabbit), decreased food consumption and increased water consumption (rat). *Developmental*: delayed ossification at maternal toxic dose (rat), none (rabbit). Relevant maternal NOAEL: 200 mg/kg bw/day (rat), 50 mg/kg bw/day(rabbit). Relevant developmental NOAEL: 400 mg/kg bw/day (rat), 190 mg/kg bw/day (rabbit). (EFSA, 2011) The weight of evidence suggests that at high concentrations, acetochlor may affect fertility or reproductive performance in the dog. Smaller effects are seen in the rat 2-generation studies at larger doses than used in the dog studies but it is unclear if the effects in the rat alone are sufficient for classification. The effects on the dog testes are of concern, but it needs to be considered whether the effect is a primary one, i.e. whether acetochlor has a direct toxicological effect on the testes or whether it is secondary to renal insufficiency. The dog studies indicate that this species is the most sensitive. The 1-year dog study by Broadmeadow (1989) also provides evidence for (delayed onset) chronic renal failure (high water consumption, high urinary volume with low specific gravities, increased plasma urea or BUN and creatinine, increased GGT, significant renal histopathology, severe neurological involvement suggestive of uremic toxicity)though not all of the classical effects associated with renal failure are noted (e.g. haematology disturbance, plasma phosphate, calcium and other electrolytes, no decrease in the relative kidney weight). Chronic renal failure is associated with gonadal dysfunction in humans and the same may be true for dogs. There was no investigation of chronic renal failure per se so even the presumption of this diagnosis is a hypothetical one based on the effects noted primarily in a single 12-month dog study with some supporting but weak evidence from the 119-day dog study by Ahmed (1980). In summary, there is sufficient concern to consider classifying acetochlor for its effects on fertility according to CLP. The effects on dog testes at 40-50 mg/kg bw/d in the 1-year studies are severe enough to cause a large reduction in mass and a suspected functional impairment. Furthermore, the 119-day dog study by Ahmed (1980) indicates a trend for a dose-related decrease (but not statistically significant) in testicular weight. There are clear indications of chronic renal failure at the high dose in one 12-month dog study but insufficient evidence to make an association between it and the testicular effects observed. The second 12-month dog study by Ahmed (1981) is more significant because there was no indication of renal failure and no lethalities, but firm evidence for testicular changes was present. There are no mechanistic studies investigating the aetiology of the testicular effects so it is not possible to be certain if they are a consequence of a primary effect by acetochlor or secondary to renal insufficiency. The RAC therefore concluded that acetochlor should be classified as Repr. 2; H361f (RAC, 2014) (Additional information provided by a CRC member from an EU Member State).
2.2.6	**Neurotoxicity/ delayed neurotoxicity, Special studies where available**	**European Union** Acute neurotoxicity: Acute NOAEL = 150 mg/kg bw/day (rat). Repeated dose neurotoxicity: 90-day NOAEL = 48 mg/kg bw/day (rat). Delayed neurotoxicity: No data (EFSA, 2011)
2.2.7	**Summary of mammalian toxicity and overall evaluation**	**European Union** Acetochlor has a moderate acute toxicity. In short term studies the dog was the most sensitive species showing decreased body weight gain and histopathological findings in kidneys and testes. Many in vitro genotoxicity studies showed positive

results but the in vivo tests did not indicate clearly a mutagenic potential. In long term studies different types of tumours were observed with increased incidences. No specific effect on the reproductive parameters was found in multigeneration studies with rats, and no evidence of teratogenicity was observed in rats or rabbits (EFSA, 2011).

Regarding reproduction, the EU Committee for Risk Assessment (RAC), concluded in 2014 that there is sufficient concern to consider classifying acetochlor for its effects on fertility according to CLP (see section 2.2.5) and concluded that the substance should be classified as Reprotoxic category 2 (RAC, 2014) (Additional information provided by CRC member from EU memberstate.

3 Human exposure/Risk evaluation

3.1 Food

European Union

Residues in food of plant origin are analysed using a common moiety method by LC-MS/MS. Data gaps have been identified for validation of the extraction and hydrolysis steps for each metabolite and ILV for the method. Consequently, no valid method is available to quantify residues in food of plant origin. For products of animal origin, a method is not required as no MRLs are proposed.

The acceptable daily intake (ADI) is 0.0036 mg/kg bw/day using the LOAEL from the 78-week mouse study with a safety factor of 300. The acute reference dose (ARfD) is 1.5 mg/kg bw, derived from the acute rat neurotoxicity study with the application of a safety factor of 100.

No chronic or acute risks were identified when the consumer exposures to food commodities are calculated using the EFSA PRIMo Model and the MRL proposed for maize grains and oil seeds; the ADI and ARfD values were not exceeded.

However, it must be highlighted that the potential consumer exposure exceeds the ADI value in many scenarios, when the predicted concentrations of the ground water metabolites are considered. In addition, intakes for toddlers and infants resulting from the water consumption are at times above the threshold value of 20% ADI recommended by the WHO, when calculations are conducted using the concentrations measured in a monitoring program conducted in Northern Italy (EFSA, 2011, EU notification).

WHO and FAO

The Meeting established an ADI of 0–0.01 mg/kg bw on the basis of a NOAEL of 1.10 mg/kg bw per day in the 78-week dietary study in mice, based on slight anaemia and an increased incidence of bronchiolar hyperplasia and interstitial fibrosis in the kidney in males observed at 11.0 mg/kg bw per day. A safety factor of 100 was applied. An ARfD of 1 mg/kg bw was established on the basis of a NOAEL of 100 mg/kg bw per day in a study of developmental toxicity in rabbits, based on decreased feed consumption, decreased body weight (GDs 6–8) and the death of two dams observed at 300 mg/kg bw per day. A safety factor of 100 was applied. (JMPR, 2015).

3.2 Air

European Union

Acetochlor is considered harmful by inhalation (acute rat LC_{50} 3.99 mg/L/4h) (EFSA, 2011).

3.3 Water

European Union

The potential human exposure is above 100% of the ADI when predicted concentrations of the ground water metabolites t-oxanilic acid, t-sulfinylacetic acid, t-sulfonic acid and s-sulfonic acid that have been concluded as relevant metabolites are taken into account.

There is a potential human exposure to metabolite t-norchloro acetochlor when surface water is abstracted for drinking water, which has been concluded as relevant from a toxicological hazard assessment perspective.

A high potential for groundwater contamination has been identified over significant areas of the EU by the metabolites t-oxanilic acid, t-sulfinylacetic acid, t-sulfonic acid and s-sulfonic acid, which have been concluded as relevant metabolites. (EFSA, 2011).

CILSS Countries

In the notification and supporting documentation, risk to human health because of high risk of surface and groundwater contamination by acetochlor and its metabolites is reported.

In the USA, due to concerns for groundwater contamination, acetochlor cannot be used on coarse soils (for ex. Sandy soil with less than 3% of organic matter) where the depth of groundwater in less than 30 feet. Acetochlor cannot be applied with any irrigation system (irrigation by flooding included) nor can it be applied by aerial application. Acetochlor cannot be applied directly on water or in areas where surface water is present. Furthermore, acetochlor must not be mixed or filled less than 50 feet from surface water or wells, unless adequate confinement or disposal measures exist. Each of these measures is intended to prevent acetochlor from migrating to ground water and/or surface water resources (US EPA, 2006).

The supporting documentation from the CILSS countries indicates the absence of an environmental management system respecting buffer strips between treated fields. Since this precaution cannot be implemented in the Sahel, the use of acetochlor entails an unacceptable risk to human health and the environment.

Further, in the CILSS countries, soils are often very poor in organic matter. Modelling values are between 1.06% to 1.36% for soils within the perimeter (Direction culture/SN-SOSUCO,2008), and the mean OC in soils near the rivers is equal to 1.06% (Ouedraogo et al, 2012). Therefore, these soils are subject to erosion and leaching. The fragile ecology of CILSS countries, sometimes characterized by torrential rainfall on soils which are very often poor in organic matter and therefore subject to erosion and leaching.

The results of the modelling study by Ouedraogo et al (2012) conclude that acetochlor had very high potential to contaminate surface water under actual usage conditions in Burkina Faso.

In a study measuring pesticide concentrations in two lakes in Burkina Faso, acetochlor concentrations up to 53.1 µg/L were measured (Soleri, 2013). Contamination of groundwater and surface water in the CILSS countries results in contamination of drinking water, since these are used as sources for drinking water. In countries like Burkina Faso, more than half the farmers (67.5 %) have a water point in their fields or nearby. Most water points are less than 100m from the fields (Toe, 2010). Water pesticide contamination via different routes may result from the proximity of water points to the fields. Water was drunk in 50% of cases, used for the preparation or the dilution of pesticides in 29.26% and for animal drinking in 26.96% (Toe, 2010). Hence the presence of acetochlor in some water courses in Burkina Faso (Soleri, 2013).

The CILSS countries concluded that using acetochlor as a pesticide under these conditions resulted an unacceptable risk to human health because of drinking water contamination.

3.4 Occupational exposure

European Union

The acceptable operator exposure level (AOEL) is 0.02 mg/kg bw/day based on the 1-year dog study, with the use of a safety factor of 100.

Two representative formulations were considered in the exposure assessment. For the formulation 'GF-675', the operator exposure is below the AOEL with the use of gloves and coverall during mixing/loading and application, and sturdy footwear during application. For the formulation 'MON 69447', the estimates with the German and UK models are above the AOEL but a bio-monitoring study measured exposures below the AOEL with the use of tractors and gloves during mixing/loading and coverall during application (EFSA, 2011; EU notification).

CILLS Countries

In the notification and supporting documentation, risks to operators are also reported:

Reference is made to the EFSA report (2011), which mentions that health risks for operators were accentuated because the estimated exposure to EC formulations recorded higher values (between 1435% and 5550%) than the acceptable operator exposure level (AOEL), despite the use of trailed sprayer and the use of gloves during mixing, loading and application. Without PPE, values up to 35550% of the AOEL are reported.

Contrary to USA and EU countries, the recommended use in Sahel countries was low volume application (knapsack sprayer) of the formulation diluted with water at doses between 2.5 and 3.5 l /ha on cotton. Frequency of application was once a crop-year. Recommended protection devices were protective clothing, goggles and gloves.

In the CILSS countries, people experience difficulties in finding suitable personal protective equipment. Farmers don't use appropriate personal protective equipment (Gomgnimbou et al., 2010, Ouedraogo et al., 2009, Toe et al, 2010). The protective equipment sold to farmers were essentially masks, boots and gloves. Masks are the most used (40% of farmers use them, 39% of which are dust masks against 1% are masks cartridge filters), followed by boots (28.8%), with the combination of the two are the least used used (4.5%). 12.62 % of farmers wear both masks and boots, while only 0.93% wears gloves, boots, overall, mask and glasses at the same time. Masks with filter cartridges are worn in combination with gloves, boots, coveralls and goggles in only 0.31% of cases. (Toe, 2010). This equipment is not specific to carry out treatments which require the full protection of operators (as for acetochlor based formulations).

3.5 Medical data contributing to regulatory decision

Not available.

3.6 Public exposure

Information available in sections 3.1. – 3.3.

3.7 Summary-overall risk evaluation

European Union

During the evaluation of this active substance, in particular the following concerns were identified: A potential human exposure above the acceptable daily intake has been identified. In addition, there is a potential for human exposure to the surface water metabolite t-norchloro acetochlor, the genotoxicity of which cannot be excluded. There is a high risk of groundwater contamination for several metabolites, a high risk for aquatic organisms and a high long term risk for herbivorous birds. Finally, the information available was not sufficient to conclude on the risk assessment for the groundwater contamination for metabolites t-norchloroacetochlor and t-hydroxyacetochlor (Commission Implementing Regulation (EU) 1372/2011).

CILSS Countries

The Sahelian Pesticides Committee recommended to stop the authorization of the pesticide formulations containing acetochlor because of the following reasons:

- Risks of water resources contamination from several metabolites including t-norchloro acetochlor;

The CILSS countries concluded that using acetochlor as a pesticide under these conditions resulted an unacceptable risk to human health because of drinking water contamination. Further, the following was taken into account (UNEP/FAO/RC/CRC.13/INF/8):

- Difficulties for the population to get adequate personal protection equipment;
- The fragile ecology of CILSS countries characterized by torrential rains on soils which are often poor in organic matter and thus highly subject to erosion and leaching;
- The absence of an environment management system respecting buffer strips between treated fields and water courses, the use of surface water as drinking water for man and animals;
- The use of groundwater as the only reservoir of drinking water;
- The existence of alternatives to the use of acetochlor.

4 Environmental fate and effects

4.1 Fate

4.1.1 Soil

European Union

In topsoil under aerobic conditions acetochlor exhibits low to moderate persistence forming the major soil metabolites t-oxanilic acid (max 17% applied radioactivity (AR)) and t-sulfonic acid (max 11.8% AR) which exhibited moderate to high persistence and t-sulfinylacetic acid (max 18% AR) which exhibited medium to high persistence. The minor soil metabolites s-sulfonic acid (max 9.8% AR) which exhibited moderate to medium persistence and t-norchloro acetochlor (max 3.3% AR) were also identified. Mineralisation of the phenyl radiolabel to carbon dioxide accounted only 0.3-3.1% of applied radioactivity (AR) after 96 days. The formation of unextractable residues was also a significant sink accounting for 15-41% AR after 84-90 days. Acetochlor exhibits high to medium mobility in soil, t-oxanilic acid, t-sulfinyl acetic acid and t-sulfonic acid exhibit very high to high mobility in soil and s-sulfonic acid and t-norchloro acetochlor exhibit very high mobility in soil. There was no indication that adsorption of either acetochlor or these 5 metabolites was pH dependent.

Acetochlor shows low to moderate persistence in soil, with DT50 values of 3.4 – 29 days in a laboratory setting and 7-17 days in the field. (EFSA, 2011; EU notification)

CILSS countries

When acetochlor enters the soil, it has high to moderate mobility based on a Koc range of 98.5 to 335. Little volatilisation from moist soil surface should occur based on its Henry's constants evaluation of 2.7 x 10-10 atm-cu m/mole. Acetochlor degradation is 8 to 15% in loamy sand during 48-day incubation period, which shows that biodegradation is an important environmental fate process in the soil. Persistence is moderate, DT_{50} = 2 to 3 months.

Adsorption occurs more easily in silty and clay soils rather than in soils with a moderate content of clay or organic matter. Acetochlor adsorbs little to soil particles which means an important potential of runoff and surface water contamination. Metabolism leads to the formation of toxic metabolites such as t-norchloro acetochlor. However, due to its moderate mobility, the risk of surface water contamination by runoff is moderate. This contamination concerns watercourses by runoff but also groundwater by infiltration (CILSS countries supporting documentation).

4.1.2 Water

European Union

In natural sediment water systems acetochlor exhibited moderate persistence degrading to the major metabolites t-oxanilic acid (2) (max. 13.1% AR in water) and t-norchloro acetochlor (6) (max10.4% AR in water 19.2% AR in sediment). The terminal metabolite, CO_2, was a small sink in the material balance accounting for only 1.4-2.7% AR at 100 days. Un-extracted sediment residues were the most significant sink for radioactivity representing 24-50% AR at 100 days.

The potential for groundwater exposure from the applied for intended uses above the parametric drinking water limit of 0.1 µg/L by parent acetochlor was concluded to be low, in geoclimatic situations that are represented by all 9 FOCUS groundwater scenarios. A high potential for groundwater contamination >0.1 µg/L over significant areas of the EU by the metabolites t-oxanilic acid, t-sulfinylacetic acid, t-sulfonic acid and s-sulfonic acid that have (on the basis of the available mammalian toxicology data) been concluded as relevant metabolites was identified. A data gap was identified for the stability of the metabolites t-norchloroacetochlor and t-hydroxyacetochlor in stored frozen groundwater samples. (EFSA, 2011, EU notification)

CILSS countries

Acetochlor is not expected to absorb to suspended matter and sediments if entering the soil. Acetochlor half-life in sewage sludge was set at 17.2 hours, which shows that biodegradation can be an important environmental fate process in water. Little volatilisation from moist soil surface is expected to occur based on the Henry's constants evaluation of that compound. A first order hydrolysis has been described

with half-life in water of 1386, 2310 and 2310 days at pH 4, pH 7 and 10, respectively. (CILSS supporting documentation,).

4.1.3	Air	**European Union** Vapour pressure of acetochlor (2.2×10^{-3} Pa at 20°C) indicates very slight volatility under the national scheme of the Netherlands. Therefore, losses due to volatilisation might be expected to be minimal. Calculations using the method of Atkinson for indirect photo-oxidation in the atmosphere through reaction with hydroxyl radicals resulted in an atmospheric half-life estimated at 2.3 hours. Therefore, the proportion of applied acetochlor that did volatilise would be unlikely to be subjected to long-range atmospheric transport. (EFSA, 2011, EU notification) **CILSS countries** A vapour pressure of acetochlor in the air of $1,67 \times 10^{-5}$ mmHg at 20 °C suggests that acetochlor will not exist in vapour and particle phases in the atmosphere to any significant extent. In the vapour phase, acetochlor will degrade in the atmosphere by reaction with hydroxyl radicals; air half-life for that reaction is estimated 2.6 hours. In particle phase, acetochlor will be removed from the atmosphere by wet or dry deposition process. Acetochlor may be sensitive to direct photolysis by sunlight. (CILSS notification)
4.1.4	Bioconcentration	**European Union** The risk of bioconcentration of acetochlor is considered to be low in fish (EFSA, 2011). The risk to fish-eating birds and mammals was assessed as low in the first-tier risk assessment but the trigger of 5 was not met for earthworm-eating birds and mammals and a data requirement was identified in the DAR. A refined risk assessment based on measured BCF in earthworms was presented in addendum 1 (of the DAR). The experts agreed that it is likely that the high content of sphagnum peat (10% instead of 5%) did not influence the outcome of the bioconcentration study because of the low Koc value of acetochlor. The experts suggested calculating the BCF on the basis of total radioactivity. The TER calculation with the BCF of 0.316 (based on total radioactivity) would result in TERs above the trigger (indicating no risk). (EFSA, 2011)
4.1.5	Persistence	**European Union** The water-sediment study (2 systems studied at 20°C in the laboratory) demonstrated acetochlor exhibited moderate persistence dissipating in the total systems with estimated single first order DT_{50} of 17-22 days (DT90 56-75 days). In soil, the substance showed low to moderate persistence ($DT_{50\ lab}$ = 3.4-29 d, 20°C, pF2 (-10kPa), $DT_{50\ field}$ = 7-17 d) (EFSA, 2011).
4.2	Effects on non-target organisms	
4.2.1	Terrestrial vertebrates	**European Union** **Terrestrial birds** Bobwhite quail, acetochlor, acute LD_{50} : 928 mg a.s./kg bw GF-675, acute LD_{50}: 1345 mg a.s./kg bw MON 69447, acute LD_{50}: 375 mg a.s./kg bw Mallard duck, acetochlor, short-term LC_{50}: 1057 mg a.s./kg bw/day Mallard duck, acetochlor, long-term NOEC: 5.5 mg a.s./kg bw/day (EFSA, 2011).
4.2.2	Aquatic species	**European Union** **Freshwater Species** **Aquatic invertebrates** *Daphnia magna* Acetochlor, 48 h (static), mortality, EC_{50}: 8.6 mg/l Acetochlor, 21 d (static), reproduction, NOEC: 0.0221 mg/l WF 2061, 48 h (static), EC_{50}: 7.4 mg/l GF-675, 48 h (static), mortality, EC_{50} >6.4 mg/l t-oxanilic acid, 48 h (static), EC_{50} >120 mg/l, NOEC = 120 mg/l

t-sulfinylacetic acid, 48 h (static), EC_{50} >120 mg/l, NOEC = 120 mg/l
t-sulfonic acid, 48 h (static), EC_{50} >120 mg/l, NOEC = 120 mg/l
t-norchloroacetochlor, 48 h (static), EC_{50}: 170 mg/l, NOEC = 100 mg/l
(EFSA, 2011)

Algae
P. subcapitata
Acetochlor, 72 h, Biomass EbC_{50} : 0.00031 mg/l, growth rate ErC_{50}: 0.00052 mg/l
Acetochlor, 120 h (static), growth rate ErC_{50}: 0.00019 mg/l GF-675, 72 h (static), Biomass EbC_{50}: 0.00077 mg/l, growth rate ErC_{50}: 0.0010 mg/l MON 69447, 72 h (static), Biomass EbCsev 0.00071 mg/l, growth rate ErC_{50}: 0.00155 mg/l t-oxanilic acid, 72 h (static), EbC_{50}: 44 mg/l, ErC_{50}: 42 mg/l, NOEr/bC: 32 mg/l,
sulfinylacetic, 72 h (static), EbC_{50}: 57 mg/l, ErC_{50}: 68 mg/l NOEbC: 32 mg/l, NOErC: 56 mg/l t-sulfonic acid, 72 hours (static), EbC_{50}: 8.1 mg/l, ErC_{50}: 17 mg/l, NOEb/rC: 3.2 mg/l t-norchloro acetochlor, 72 hours (static), EbC_{50} : 0.34 mg/l, ErC_{50} : 0.49 mg/l, NOEbC: 0.12 mg/l, NOErC: 0.24 mg/l s- sulfonic acid, 72 hours (static), EbC_{50} and ErC_{50} and NOEbC all >124 mg/l (EFSA, 2011)

Aquatic plants
Lemna gibba
Acetochlor, 7 d EC_{50} (frond no): 0.0027 mg/l
MON 69447, 7 d EC_{50} (frond no): 0.00257 mg/l
GF-675, 7 d EC_{50} (frond no) > 0.00054mg/l t-oxanilic acid, 7 days static, EC_{50} (frond n°) >123 mg/l, ErC_{50} >123 mg/l, NOEC (both): 123 mg/l
t-sulfinylacetic acid, 7 days static, EC_{50} (frond n°) >112 mg/l, ErC_{50} >112 mg/l, NOEC (both): 112mg/l t-sulfonic acid, 7 days static, EC_{50} (frond n°) > 140 mg/l, ErC_{50} > 140 mg/l, NOEC > 140 mg/l
s-sulfonic, 7 days static, EC_{50} (frond n°) > 150 mg/l, ErC_{50} > 150 mg/l, NOEC (both) > 150 mg/l
Norchloroacetochlor, 7 days static, EC_{50} (frond n°): 19 mg/l, ErC_{50}: 49 mg/l, NOEC (both): 4.8 mg/l (EFSA, 2011)

Fish
Oncorhynchus mykiss, acetochlor, 96h (static), mortality EC_{50}: 0.36 mg/l
Oncorhynchus mykiss, 60 day (flow-through), growth NOEC: 0.13 mg/l
Bluegill sunfish, GF 675, 96 h (static) mortality EC_{50}: 1.07 a.s. mg/l
Oncorhynchus mykiss
MON 69447, 96 h (flow-through), mortality EC_{50}: 0.547 a.s. mg/l
t-oxanilic acid, 96 h (static), mortality LC_{50} >93 mg/l
t-sulfinylacetic acid, 96 h (static), mortality LC_{50} >120 mg/l
t-sulfonic acid, 96 h (static), mortality LC_{50} >180 mg/l
t-norchloro acetochlor acid, 96 h (static), mortality LC_{50}: 42 mg/l (EFSA, 2011)

4.2.3 Honeybees and other arthropods

European Union
Honey Bee
Acetochlor, acute LD_{50} oral >100 a.s. µg/bee, contact > 200 µg/bee
Preparation WF-2061, MON 69447 and the metabolites, t-oxanilic acid, t-sulfinylacetic acid, t-sulfonic acid, s-sulfonic acid, acute LD_{50} oral and contact all >86.7 µg/bee, (EFSA, 2011)

Other Arthropod Species
Laboratory tests
Mortality with GF-675
Typhlodromus pyri, LR_{50}: 831 g a.s/ha
Aphidius rhopalosiphi, LR_{50}:156 g a.s/ha (EFSA, 2011)
P. *cupreus*, $LR^{5}9_{50}$ M = 0% at 2000 g a.s./ha
Chrysoperla carnea, LR_{50} M = 0% at 2000 g a.s./ha
(EFSA, 2011)

4.2.4	**Earthworms**	**European Union** **Earthworm** *Eisenia foetida* Acetochlor, acute 14-days LC_{50}: 105.5 mg a.s./kg dw soil MON69447, acute 14-days LC_{50}: 221 mg a.s./kg dw soil Oxanilic acid, t-sulfinylacetic acid, t-sulfonic acid, s-sulfonic acid; acute 14-days LC_{50} >500 mg a.s./kg dw soil Oxanilic acid, chronic NOEC: 3.39 mg a.s./kg dw soil t-sulfinylacetic acid, NOEC: 3.44 mg a.s./kg dw soil t-sulfonic acid, NOEC: 3.71 mg a.s./kg dw soil s-sulfonic acid, NOEC: 10.5 mg a.s./kg dw soil (EFSA, 2011)
4.2.5	**Soil microorganisms**	**European Union** The effects of the lead acetochlor based formulations were tested on soil microbial respiration and nitrogen transformation. The risk to soil non-target micro-organisms from acetochlor is considered to be low for the representative uses evaluated. (EFSA, 2011).
4.2.6	**Terrestrial plants**	**European Union** Studies with technical acetochlor and different formulations on the influence on seedling emergence and plant vigour are available. The risk assessment presented in the DAR was based on species sensitivity distribution on endpoints for 21 plant species. Overall it is concluded that a high risk to non-target plants cannot be excluded and risk mitigation measures comparable to a no spray buffer zone (in-field) of 5 m is required. (EFSA, 2011).

5 Environmental Exposure/Risk Evaluation

5.1	**Terrestrial vertebrates**	**European Union** The short-term toxicity-exposure ratio (TER) for birds and the acute and long-term TERs for mammals were above the trigger of 10 and 5 in the first-tier risk assessment. A residue decline study was submitted. The acute risk to herbivorous birds was sufficiently addressed on the basis of measured residues. However, the suggested 'proportion of different food types in the diet' (PD) and 'proportion of diet obtained in treated area' (PT) values to refine the long-term risk to herbivorous birds were assessed and considered as not supported by the submitted data. The refined risk assessment for insectivorous birds based on crested lark (*Galerida cristata*) was agreed by the meeting. The risk from consumption of contaminated water was assessed as low for mammals. It was agreed in the expert meeting, that the risk to mammals is low. However, a high acute risk was indicated for birds for post-emergence applications where accumulation of water in leaf axils of maize plants can occur. The risk from secondary poisoning of fish-eating birds and mammals was assessed as low in the first tier but further refinement was required for earthworm-eating birds and mammals. The risk was sufficiently addressed using data from a bioconcentration study with earthworms. The risk from soil metabolites was considered to be low because their log Pow is <3 suggesting a low potential of bioconcentration and bioaccumulation in the food chain. Endpoints from acute toxicity studies with rats were available for the major plant metabolite N-oxamic acid (68) and for metabolite 3 (t-sulfinylacetic acid). No information on the toxicity to birds was available. In the risk assessment it was assumed that the metabolites have a similar toxicity to birds as the parent. The acute and long-term TERs for birds and mammals were above the triggers of 10 and 5. However some uncertainty remains because of the high proportion of unidentified residues in the residue trials (EFSA, 2011). **CILSS Countries** In the supporting documentation, high acute risk to birds from uptake of contaminated drinking water was indicated for the post emergence applications and high long term risk for herbivorous birds was mentioned.

5.2	**Aquatic species**	**European Union** Acetochlor is very toxic to all groups of aquatic organisms and a high risk was indicated in the risk assessment with the FOCUS model step3 PECsw. A risk refinement based on endpoints from a static mesocosm and from a mesocosm with a pulsed exposure regime was used to refine the risk in lentic and lotic water bodies. The experts agreed that the 'no observed adverse effect concentration' (NOAEC) of 0.2 µg acetochlor/L for lentic water bodies and the NOAEC of 2 µg acetochlor/L for lotic water bodies should be used in the risk assessment together with an assessment factor of 2-3. No FOCUS model step 4 scenario resulted in a TER exceeding the trigger of 2 even when no-spray buffer zones of 20m and vegetated filter strips of 20m were applied to mitigate the risk. Overall it is concluded that the risk to aquatic organisms from exposure to acetochlor is high for the representative uses evaluated. The risk from metabolites in water and sediment was assessed as low. The bioconcentration potential of acetochlor was assessed as low (EFSA, 2011). **CILSS Countries** In the supporting documentation, it is mentioned that acetochlor is very toxic to all groups of aquatic organisms and there is a high risk to aquatic organisms.
5.3	**Honey bees**	**European Union** The risk to bees, soil macro-organisms, organic matter breakdown and biological methods of sewage treatment was assessed as low for the representative uses of acetochlor (EFSA, 2011).
5.4	**Earthworms**	**European Union** The acute risk of acetochlor to earthworms was assessed as low. No long-term risk assessment is triggered because the representative uses cover only one application per year and the field DT90 is <100 days. The acute and long-term risk from soil metabolites to earthworms was assessed as low (EFSA, 2011).
5.5	**Soil microorganisms**	The risk to soil-micro-organisms was assessed as low for the representative uses of acetochlor (EFSA, 2011).
5.6	**Summary – overall risk evaluation**	**European Union** During the evaluation of this active substance, in particular the following concerns were identified: There is a high risk of groundwater contamination for several metabolites, a high risk for aquatic organisms and a high long term risk for herbivorous birds. **CILSS Countries** The Sahelian Pesticides Committee recommended stopping the authorization of the pesticide formulations containing acetochlor because of the following reasons: • Risks of water resources contamination from several metabolites including t-norchloro acetochlor; • High risk to aquatic organisms and long term risks to herbivorous birds Further, the following was taken into account (UNEP/FAO/RC/CRC.13/INF/8): • The fragile ecology of CILSS countries characterized by torrential rains on soils which are often poor in organic matter and thus highly subject to erosion and leaching; • The absence of an environment management system respecting buffer strips between treated fields and water courses, the use of surface water as drinking water for man and animals; • The existence of alternatives to the use of acetochlor.

Annex 2 – Details on final regulatory actions reported

Country Name: European Union

1	**Effective date(s) of entry into force of actions**	23 June 2013
	Reference to the regulatory document	Commission Implementing Regulation (EU) No 1372/2011 of 21 December 2011 concerning the non-approval of the active substance acetochlor, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending Commission Decision 2008/934/EC (Official Journal of the European Union L 341, 22.12.2011, p. 45-46). https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32011R1372
2	**Succinct details of the final regulatory action(s)**	It is prohibited to place on the market or use plant protection products containing acetochlor in the European Union. Acetochlor is not approved for placing on the market pursuant to Regulation (EC) No. 1107/2009 concerning the placing of plant protection products on the market (which replaces Directive 91/414/EEC). All authorisations for plant protection products containing acetochlor had to be withdrawn by the Member States by 23 June 2012 and all uses of plant protection products containing acetochlor are prohibited as of 23 June 2013 at the latest.
3	**Reasons for action**	Reduction of risk from the use of plant protection products containing acetochlor to human health and the environment.
4	**Basis for inclusion into Annex III**	The final regulatory action was taken to protect human health and the environment. The regulatory action was based on a risk evaluation taking into account the prevailing conditions in the EU.
4.1	**Risk evaluation**	During the evaluation of this active substance, in particular the following concerns were identified: A potential human exposure above the acceptable daily intake has been identified. In addition, there is a potential for human exposure to the surface water metabolite t-norchloro acetochlor, the genotoxicity of which cannot be excluded. There is a high risk of groundwater contamination for several metabolites, a high risk for aquatic organisms and a high long term risk for herbivorous birds. Finally, the information available was not sufficient to conclude on the risk assessment for the groundwater contamination for metabolites t-norchloro acetochlor and t-hydroxyacetochlor (Commission Implementing Regulation (EU) 1372/2011). **Safety Values:** Acceptable Daily Intake (ADI): 0.0036 mg/kg bw/day (78-week mouse study and Safety Factor of 300 (3x100); the additional factor of 3 was used because of the use of the LOAEL). Acceptable Operator Exposure Level (AOEL): 0.02 mg/kg bw/day (1-year dog study with Safety Factor of 100). Acute Reference Dose (ARfD): 1.5 mg/kg bw/day (acute neurotoxicity in rat and safety factor of 100). (EU and CILSS notifications) (EFSA, 2011)
4.2	**Criteria used**	Risk to human health and the environment.
	Relevance to other States and Region	The use of pesticides containing acetochlor may cause similar problems to health and the environment in other countries (EU notification).
5	**Alternatives**	The notifying Party did not provide information on alternatives for the use of acetochlor.
6	**Waste management**	The notifying Party did not provide information on waste management of acetochlor.
7	**Other**	None.

Country Name: Burkina Faso, Cabo Verde, Chad, the Gambia, Guinea-Bissau, Mali, Mauritania, the Niger, Senegal and Togo (CILSS countries)

1	**Effective date(s) of entry into force of actions**	20 March 2017
	Reference to the regulatory document	Decision N 002/CM/2017 of CILSS coordinating Ministry
2	**Succinct details of the final regulatory action(s)**	On recommendation of the Sahelian Pesticide Committee (CSP), Decision N°002/MC/2017 to ban all products containing acetochlor was signed on 20 March 2017 by CILSS coordinating Ministry. The final regulatory action entered into force on 20 March 2017. The use of all pesticides containing acetochlor has been banned due to its potential for water contamination. The import, manufacture for domestic use, distribution and sale are also banned.
3	**Reasons for action**	Reduction of risk from the use of plant protection products containing acetochlor to human health and the environment.
4	**Basis for inclusion into Annex III**	The final regulatory action was taken to protect human health and the environment. The regulatory action was based on a risk evaluation taking into account the prevailing conditions in the CILSS countries.
4.1	**Risk evaluation**	The Sahelian Pesticides Committee recommended stopping the authorization of the pesticide formulations containing acetochlor because of the following reasons: • Risks of water resources contamination from several metabolites including t-norchloro acetochlor; • Unacceptable risk to human health because of drinking water contamination • High risk to aquatic organisms and long term risks to herbivorous birds. Further, the following was taken into account (UNEP/FAO/RC/CRC.13/INF/8): • Difficulties for the population to get adequate personal protection equipment; • The fragile ecology of CILSS countries characterized by torrential rains on soils which are often poor in organic matter and thus highly subject to erosion and leaching; • The absence of an environment management system respecting buffer strips between treated fields and water courses, the use of surface water as drinking water for man and animals; • The use of groundwater as the only reservoir of drinking water; • The existence of alternatives to the use of acetochlor.
4.2	**Criteria used**	Risk to human health and the environment.
	Relevance to other States and Region	The use of pesticides containing acetochlor may cause similar problems to health and the environment in other countries (CILSS countries notification).
5	**Alternatives**	Alternatives to the use of acetochlor based formulations do exist. As an alternative, selective pesticide formulations are registered and authorised for sale in CILSS countries. Several selective pesticide formulations can be found in the global list of pesticides registered by the Sahelian Pesticide Committee (CSP) for maize and for cotton (CSP, 2016, see website: www.insah.org) (CILSS countries notification).
6	**Waste management**	The notifying Party did not provide information on waste management of acetochlor.
7	**Other**	None.

Annex 3 – Addresses of designated national authorities

CILSS Countries: Burkina Faso, Cabo Verde, Chad, the Gambia, Guinea-Bissau, Mali, Mauritania, the Niger, Senegal and Togo

Burkina Faso Ministère de l'Agriculture et des Aménagements Hydrauliques Direction Générale des Productions Végétales Direction de la Protection des Végétaux et du Conditionnement DPVC 01 BP: 5362 Ouagadougou 01 OUATTARA Moussa Directeur de la Protection de Végétaux et du Conditionnement	Phone: +226 25361915 / +226 71353315 E-mail: outtmouss@yahoo.fr / dpvcagriculture@yahoo.fr
Cabo Verde Ministère de l'Agriculture et de l'Environnement (MAA) Direction Générale de l'Agriculture, Sylviculture et Elevage (DGASP) BP 278 Praia Ilha de Santiago Cabo Verde Celestino Gomes Mendes Tavares AND Pesticides	Phone: +238 5160089 E-mail: Celestino.Tavares@maa.gov.cv
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Togo Ministry of Agriculture BP 5054 Nouakchott-Mauritanie Sow Moussa Mamadou Technical advisor responsible for the agricultural sector and plant protection	Phone +222 46463939 Fax +222 45257475 E-mail sowmoussa635@yahoo.fr

European Union	
European Commission DG Environment BU-9, 06/164 B-1049 Brussels Belgium Dr. Juergen Helbig Policy Officer	**Phone** +32 2 298 8521 **Fax** +32 2 296 7617 **E-mail** Juergen.Helbig@ec.europa.eu

Annex 4 – References

Regulatory actions

European Union

Commission Implementing Regulation (EU) No 1372/2011 of 21 December 2011 concerning the non-approval of the active substance acetochlor, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending Commission Decision 2008/934/EC (Official Journal of the European Union L 341, 22.12.2011, p. 45-46). http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32011R0341

CILSS countries

Decision N°002/CM/2017 of CILSS coordinating Ministry

Supporting Documentation

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WHO and FAO

JMPR, 2015: Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group on Pesticide Residues Geneva, Switzerland, 15-24 September 2015: Acetochlor.

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